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K000180
Page 1 of 3

MAR - 2 2001

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:	Date of Preparation: January 18, 2000
Company / Institution name: **Richard Wolf Medical Instruments Corp.**	FDA establishment regulation number: 14 184 79
Division name (if applicable): N.A.	Phone number (include area code): (847) 913-1113
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City:	State/Province:	Country:	ZIP/Postal Code:
Vernon Hills	Illinois	USA	60061

Contact name: Mr. Robert L. Casarsa

Contact title: Quality Assurance Manager

Product Information:	
Trade name: Transanal Endoscopic Microsurgery (TEM) Combination System and Instrument Set	Model number: 2232.621, .631
Common name: Transanal Endoscopic Surgical Insufflator System and Instrument Set	Classification Name: Insufflator, Laparoscopic and Instruments

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K910716	1 Combination Endo-Surgical Device Model 2144.00	1 Richard Wolf
2 K981334	2 Laparo CO_2 Pneu 2232	2 Richard Wolf
3	3 Video-operating-proctoscopes for anal surgery	3 Karl Storz
4	4	4

1.0 Description

Transanal Endoscopic Microsurgery (TEM) Combination System consists of the CO_2-Pneu and a pump. It can be used for two selectable operation principles:

1. TEM Mode: The TEM System is used for inflating the rectal cavity by CO_2 gas. Inflation is maintained under continuous insufflation with pressure monitoring.

A1-1C

2. Laparoscopy Mode: The Pneu is used for establishing the pneumoperitoneum by insufflating CO_2 gas in the abdominal cavity. The TEM pump is not working in this mode.

The instruments for transanal endoscopic microsurgery (TEM) are specially designed for the rectal cavity. The operation site is endoscopically imaged with a round rectoscope with a 40mm diameter which is affixed to the operating table. A stereoscopic telescope or a monocular video telescope allow preparation under microsurgical conditions. Up to three surgical instruments can be simultaneously be insertion for the operation.

2.0 Intended Use

Transanal Endoscopic Microsurgery (TEM) combination system and the instrument set for the TEM procedure are designed to provide access to the rectal cavity and accessible part of the lower sigmoid colon using a stereo and/or monocular endoscope under gas tight conditions for the excision of polyps and/or the removal of tumors that have been previously staged.

The TEM combination system is used for pressure controlled insufflation of the colon with CO_2 gas for transanal microsurgery (TEM). In addition, the telescope window can be flushed with sterile saline, and blood, secretion and smoke can be pumped from the rectal cavity.

The Laparo CO_2-Pneu automatic insufflator can be used without the TEM Pump for establishing and maintaining pneumoperitoneum with CO_2 gas during diagnostic and operative laparoscopy.

The Instrument Set for TEM is used for the transanal endoscopic microsurgery. Endoscopic accessories are inserted through an OP rectoscope with stereo-endoscope under gas tight conditions.

3.0 Technological Characteristics

The TEM Pneu monitors the rectal pressure via additional tubing to the instrument set. The advantage is a constant pressure without collapse of the rectum during measurement period. The maximum insufflation rate is 8l/min. The pressure and flow values are checked by a microprocessor control.

If the intrarectal pressure is more than 3mmHg and the insufflation is activated, the TEM Pump provides additional continuous suction. The suction rate can be set between 0.5 and 1.5 l/min.

If required the optical window is cleaned with sterile saline from blood and secretion. The suction and rinsing are controlled by a foot switch.

In the laparoscopy mode, the insufflation alternates with pressure measurement and is executed by the same tube. These functions in the laparoscopy mode are the same as in the device cleared in 510(k) submission K910716: "Laparo CO2-Pneu (Laparoscopic Insufflator)". The flow rate can be preselected between 1 l/min and 30 l/min in steps of 1 l/min.

The stereo endoscope with moveable eyepieces is used together with the documentation endoscope for video monitoring. Laparoscopes can be used with an additional suction and irrigation tube.

The length of the submitted instruments have been modified for ergonomic reasons. The modified devices facilitate transanal endoscopic microsurgery (TEM).
Tubes connected to the basic part vary in length and the distal tips are straight or oblique.
The obturators are made of stainless steel to ensure a fixed diameter.

4.0 Substantial Equivalence

Transanal Endoscopic Microsurgery (TEM) Combination System and Instrument Set is substantially equivalent to existing 510(k) devices sold by Richard Wolf. The differences do not diminish the safety or effectiveness of the device.

5.0 Performance Data

No performance data generated.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

The Transanal Endoscopic Surgery (TEM) Combination System was designed and tested to guarantee the safety and effectiveness during the expected life time of the device when used according to the instruction manual.

By: Robert L. Casarsa Date: June 29, 2000

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2001

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
VERNON HILLS IL 60061

Re: K000180
Transanal Endoscopic Microsurgery (TEM)
Combination System and Instrument Set
Dated: January 4, 2001
Received: January 5, 2001
Regulatory Class: II
21 CFR §884.1730/Procode: 85 HIF
21 CFR §876.1500/Procodes: 78 FCX, FJL, and GCM
21 CFR §876.4300/Procode: 78 KNS

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use

510(k) Number (if known): K000180

Device Name: Transanal Endoscopic Microsurgery (TEM) Combination System And Instrument Set

Intended Use:

Transanal Endoscopic Microsurgery (TEM) combination system and the instrument set for the TEM procedure are designed to provide access to the rectal cavity and accessible part of the lower sigmoid colon using a stereo and/or monocular endoscope under gas tight conditions for the excision of polyps and/or the removal of tumors that have been previously staged.

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Contraindications:

WARNING! The Laparo CO_2-Pneu has a hight flow rate. The device cannot be used for hysteroscopy. The device must not be used for inflating the cabum uteri.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter

Based on the patient's general condition, the attending physician must determine if the procedure is appropriate. For further information, refer to the current technical literature.

Combinations:

The instrument Set for Transanal Endoscopic microsurgery (TEM) is used in connection with the TEM Combination System 2232, as well as light sources, video cameras with lenses, HF units, and endoscopic accessories.

The combined use of the multiple devices must correspond with the intended use and the relevant technical data, i.e. working length, diameter, etc. Comply with the instruction manuals of the devices used. Comply with instruction manual E111 for HF applications.

Important! In addition to the TEM Combination System Instruction Manual, comply with the instruction manuals used in combination with this product.

Electromagnetic interference or other influences which may occur between the product and other products can cause faults or malfunctions.

Warning! Danger of potentially fatal gas or air embolism.

Purge the connection tubes with a sufficient amount of CO_2 before use. The use of devices applying additonal gaseous media in combination with the TEM Combination System or Laparo CO_2 Pneu automatic insufflator is the exclusive responsibility of the user.

Warning! Danger of intrarectal/intra-abdominal overpressure when a second gas source is used.

To eliminate the potential of deactivating the pressure release function (venting) of the Laparo CO2 Pneu automatic insufflator, the user must employ additional visual or manual pressure monitoring if argon plasma coagulators are used. The pressure release function can be deactivated as a consequence of effects such as a kinked insufflation tube or a closed instrument tap. The preselected gas flow rates of an Argon plasma coagulator should not exceed 2 L/min. Activate the Argon plasma coagulator only for a short time.

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Concurrence of CDRH Office of Device Evaluation (ODE)

David C. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000180

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Per 21 CRF 801.109